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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,857	10/25/2001	Mark G. Erlander	485772002900	1235

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EXAMINER

HASHEMI, SHAR S

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,857

Applicant(s)

ERLANDER ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: "Notice to Comply".

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

A) The "Brief Description of the Drawings" section is objected to because each figure does not have a corresponding description. For example, Figures 1C is not described. It is suggested to provide a description for each figure.

B) The use of the trademark "Sequenase" (page 23, line 28) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademark is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

C) This application contains sequence disclosures (page 37, line 12) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825.

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Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Regarding claim 9, the phrase "combinations thereof" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "combinations thereof"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). It is recommended to incorporate Markush language.

B) Claim 10 recites the limitation "the aRNA/DNA hybrids" on page 47, line 21. There is insufficient antecedent basis for this limitation in the claim.

C) Claims 10-16 are indefinite because the phrase "and/or" in claim 10 is vague. It is unclear as to whether the claim refers to forming and transcribing or forming or transcribing.

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D) Claim 17-30 & 32 are indefinite because claim 17 recites the limitations "the mRNA/cDNA hybrids" (page 50, line 4) and "the aRNA/DNA" (page 50, line 20). There is insufficient antecedent basis for these limitations in the claim.

E) Claims 1-16 & 31 are indefinite because the phrase "said sequences" on page 45, line 7 of claim 1 is confusing. It is unclear as to whether the phrase "said sequences" refers to the RNA sequences or sequences present in target polynucleotide.

F) Claims 1-32 are indefinite because the abbreviation "(aRNA)" in claims 1, 10, 17 & 18 is confusing. The term "aRNA" is known in the art as "antisense RNA." Claim 1 states the "aRNA" means "amplified RNA." It is unclear as to which definition "aRNA" refers to.

G) Claims 1-32 are indefinite because the limitation "random primer region" in claims 1, 6, 7, 12, 13, 17, 23, 24, 26, 27 & 28 is confusing. The term "random primer" is known in the art as a random combination of nucleotides. It is unclear as to how these terms could be distinguished from one another. Moreover, it is unclear whether the oligonucleotide recited in the claims is the primer or contains primer region.

H) Claim 14 and 25 are indefinite because the phrase "polymerase activity comprises exonuclease deficient Klenow and Taq polymerase" is confusing. It is unclear as to whether the claim refers to one polymerase or a combination of polymerase. It is suggested to delete "comprises" and insert "is selected from the group consisting of..."

I) Claim 15, 16, 29 & 30 are indefinite because the term "known primer" is vague. It is unclear as to whether the term "known primer" refers to a primer containing non-degenerate or degenerate sequences.

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J) Claims 1 & 17 recite the limitation "mRNA." There is insufficient antecedent basis for this limitation in the claim. If the limitation "mRNA" refers to "single stranded target polynucleotide," then the phrase "single stranded target polynucleotide" should be changed to "mRNA."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 2002/0137709 A1 September 26, 2002) in view of Adams et al (US 6,297,365 B1 October 2, 2001).

Lin et al teach a method of amplifying RNA sequences complementary to one or more than one target polynucleotide that is single stranded or made single stranded (page 12, claim 1). They teach forming double stranded cDNA templates containing sequences present in a target polynucleotide, wherein the sequences are operably linked to a promoter region by annealing the single stranded target polynucleotide with a first oligonucleotide comprising a primer operably linked to a promoter region to form a first complex (pg. 12, claim 1, step a), synthesizing a first strand cDNA by reverse transcription of the first complex (pg. 12, claim 1, step b), annealing the first strand cDNA, after denaturing the mRNA/cDNA hybrid or degrading the RNA from the

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hybrid, with a plurality of second oligonucleotides comprising a random primer region to form a population of second complexes (pg. 12, claim 1, step e), forming double stranded cDNA templates from the population of second complexes with DNA polymerase activity (pg. 13, claim 5), transcribing the cDNA templates with an RNA polymerase capable of initiating transcription via the promoter region to produce amplified RNA containing sequences complementary to the target polynucleotide (pg. 13, claim 6). They teach the target polynucleotide is mRNA (pg. 12, claim 1). They teach more than one target polynucleotide are a cellular mRNA preparation (see Example 3, page 9). They teach the first oligonucleotide comprises a primer containing a poly dT sequence (pg. 13, claim 14). They teach the poly dT sequence is at least about eight dT in length (pg. 3, par. 37). They teach the random primer region comprises at least about six random nucleotides or at least about nine random nucleotides (pg. 3, par. 38). They teach DNA polymerase activity is DNA dependent (pg. 13, claim 6). They claim the DNA dependent polymerase activity is Taq polymerase (pg. 13, claim 6). They teach where the above annealing, synthesizing, annealing, forming and transcribing components of the method are repeated to further amplify the RNA sequences complementary to one or more than one target polynucleotide (pg. 12, claim 2). They teach the oligonucleotide comprises a known primer primer sequence that is complementary to the 3' region of the aRNA (pg. 13, claim 13). They teach the first oligonucleotide comprise a T7 promoter region (pg. 13, claim 11). They teach the third oligonucleotide comprises a T3 or SP6 promoter region (pg. 13, claim 11).

Lin et al do not teach exonuclease activity and exonuclease deficient Klenow.

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Adams et al teach exonuclease activity and exonuclease deficient Klenow (col. 16, line 24). They teach amplification procedures using exonuclease deficient Klenow and Taq polymerase (col. 16, lines 16-30).

One of ordinary skill at the time the invention was made would have been motivated to apply Adams et al's exonuclease deficient Klenow to Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production (col. 7, lines 35-50). It would have been prima facie obvious to apply Adams et al's exonuclease deficient Klenow to Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production.

SUMMARY

6. No claims allowed.

CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and

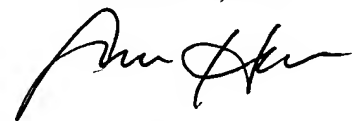
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whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

October 31, 2002



JEFFREY SIEW
PRIMARY EXAMINER

11/4/02